K073063

510(k) SUMMARY

Biolitec Inc.'s
15W Ceralas Diode 1470nm Laser System (Model D1470)

Submitter's Name, Address, Telephone Number, Contact Person and Date Prepared

Hogan & Hartson
555 13th Street NW
Washington DC 20004

Phone: (202) 637-5794
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Contact Person: Jonathan S. Kahan

Date Prepared: December 5, 2007

Name of Device and Name/Address of Sponsor

15W Ceralas D 1470nm Diode Laser (Model D1470)

Biolitec, Inc.
515 Shaker Road
East Longmeadow, MA 01028

Common or Usual Name

Diode Laser

Classification Name

Laser, Surgical Diode Laser System

Predicate Devices

CoolTouch Model CT3S Nd:YAG laser (K040921)
CoolTouch CTEV and CT3S 1320 Nd:YAG laser (K051434)
CoolTouch CTEV Nd:YAG laser (K061618)
CoolTouch LC160 CTEV Nd:YAG laser (K062210)
Sciton, Inc., Profile Multi-Platform System (K060033)

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Intended Use / Indications for Use

The Ceralas D1470 is a diode laser that is intended for delivery of laser light to soft tissue in non-contact mode during general surgery procedures. The device is indicated for the treatment of reflux of the saphenous veins associated with varicose veins and varicosities.

Technological Characteristics

The Ceralas D1470 has substantially similar technological characteristics as compared to the CoolTouch CTEV Nd:YAG laser, the CoolTouch CT3S Nd:YAG laser, and the Sciton, Inc., Profile Multi-Platform System. The Ceralas D1470 contains an ELVeS Kit for gaining access to the vasculature to treat varicose veins and varicosities associated with superficial reflux of the saphenous veins.

Performance Data

Performance testing of the Ceralas D1470 demonstrates no significant difference as compared to the cleared CoolTouch CTEV Nd:YAG laser, the CoolTouch CT3S Nd:YAG laser, and the Sciton, Inc., Profile Multi-Platform System.

Substantial Equivalence

The Ceralas D1470 is as safe and effective as the CoolTouch CTEV Nd:YAG laser, the CoolTouch CT3S Nd:YAG laser, and the Sciton, Inc., Profile Multi-Platform System. The Ceralas D1470 has the same intended uses and similar indications, technological characteristics, and principles of operation as its predicate devices. The minor technological differences between the Ceralas D1470 and its predicate device raises no new issues of safety or effectiveness. Thus, the Ceralas D1470 is substantially equivalent.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 27 2008

Biolitec, Inc.
% Hogan & Hartson, L.L.P.
Mr. Jonathan S. Kahan
Columbia Square
555 Thirteenth Street, Northwest
Washington, District of Columbia 20004

Re: K073063
Trade/Device Name: 15W Ceralas D 1470nm Diode Laser (Model D1470)
Regulation Number: 21 CFR 878.4810
Regulation Name: Laser surgical instrument for use in general and plastic surgery and in dermatology
Regulatory Class: II
Product Code: GEX
Dated: December 5, 2007
Received: December 5, 2007

Dear Mr. Kahan:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if known): K073063

Device Name: 15W Ceralas D 1470nm Diode Laser (Model D1470)

Indications for Use:

The Ceralas D1470 is a diode laser that is intended for delivery of laser light to soft tissue in non-contact mode during general surgery procedures. The device is indicated for the treatment of reflux of the saphenous veins associated with varicose veins and varicosities.

Prescription Use __X__ AND/OR Over-The-Counter Use____
(Part 21 C.F.R. 801 Subpart D) (21 C.F.R. 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE -- CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

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(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K073063